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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,910	07/11/2001	Haodong Li	PF126P2	7856

22195 7590 05/15/2003

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	9

DATE MAILED: 05/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/901,910	LI ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-27 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14, drawn to a method of stimulating angiogenesis in a mammal, comprising the administration of a polynucleotide encoding CTGF-2, or an active fragment or derivative thereof, classifiable in class 435, subclass 6.

II. Claims 15-23, drawn to a method of stimulating angiogenesis in a mammal, comprising the administration of a CTGF-2 polypeptide, or an active fragment or derivative thereof, classifiable in class 435, subclass 4.

III. Claim 24, drawn to a method of inhibiting tumor growth by administering an antibody or antibody fragment that bind to CTGF-2, classifiable in class 424, subclass 130.1^{+}.

IV. Claims 25 and 26, drawn to an antibody or antibody fragment that binds to a protein whose sequence consists of the protein encoded by the cDNA contained in ATCC Deposit No. 75804 or SEQ ID NO: 2, classifiable in class 424, subclass 130.1.

V. Claim 27, drawn to an antibody or antibody fragment that binds to a protein whose sequence consists of SEQ ID NO: 7, classifiable in class 424, subclass 130.1.

The inventions are distinct, each from the other because of the following reasons:

Although the methods of Groups I and II are related because they encompass a method of stimulating angiogenesis in a mammal, they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related methods, restriction is deemed to be proper because these method constitute patentably distinct inventions for the following reasons: They employ different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the polynucleotide encoding CTGF-2, or an active fragment or derivative thereof of Group I would not encompass all of the art relevant to the CTGF-2 polypeptide, or an active fragment or derivative thereof of Group II. They are materially distinct methods, which differ in reagents and/or dosages and/or schedules used, response variables, and criteria for success. The differences between Inventions I and II are further underscored by their different classifications and independent search status. Thus, they are unrelated and patentably distinct from each other.

Inventions of Groups I and III are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions of Groups I and III are unrelated and distinct because they employ different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the polynucleotide encoding CTGF-2, or an active fragment or derivative thereof of Group I would not encompass all of the art relevant to the

antibody or antibody fragment that bind to CTGF-2 of Group III. They are materially distinct methods, which differ in reagents and/or dosages and/or schedules used, response variables, and criteria for success. The differences between Inventions I and III are further underscored by their different classifications and independent search status. Thus, they are unrelated and patentably distinct from each other.

Inventions of Groups II and III are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions of Groups II and III are unrelated and distinct because they employ different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the CTGF-2 polypeptide, or an active fragment or derivative thereof of Group II would not encompass all of the art relevant to the antibody or antibody fragment that bind to CTGF-2 of Group III. They are materially distinct methods, which differ in reagents and/or dosages and/or schedules used, response variables, and criteria for success. The differences between Inventions II and III are further underscored by their different classifications and independent search status. Thus, they are unrelated and patentably distinct from each other.

The invention of Group IV is related to the method invention of Group III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case, the products can be used in materially different processes of use. For example, the antibody or antibody fragment that binds to a protein whose sequence consists of the protein encoded by the cDNA contained in ATCC Deposit No. 75804 or SEQ ID NO: 2 of Group IV can be used to identify CTGF-2 protein expression in mammalian cells, which is a materially different process than a method of inhibiting tumor growth by administering an antibody or antibody fragment that bind to CTGF-2 as in Group III.

The invention of Group V is related to the method invention of Group III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products can be used in materially different processes of use. For example, the antibody or antibody fragment that binds to a protein whose sequence consists of SEQ ID NO: 7 of Group IV can be used to identify alternative forms of CTGF-2 protein expression in mammalian cells, which is a materially different process than a method of inhibiting tumor growth by administering an antibody or antibody fragment that bind to CTGF-2 as in Group III.

Inventions of Groups IV and V are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions of Groups IV and V are unrelated and distinct because they are different molecules with different chemical and physical structures so that

independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the antibody or antibody fragment that binds to a protein whose sequence consists of the protein encoded by the cDNA contained in ATCC Deposit No. 75804 or SEQ ID NO: 2 of Group IV would not encompass all of the art relevant to the antibody or antibody fragment that binds to a protein whose sequence consists of SEQ ID NO: 7 of Group V. They are materially distinct compositions since SEQ ID NO: 7 is an alternative cDNA sequence of CTGF-2 and the protein encoded by the cDNA contained in ATCC Deposit No. 75804 or SEQ ID NO: 2 are the actual cDNA sequence of CTGF-2. Thus, they are unrelated and patentably distinct from each other.

Claims 13 and 23 are generic to a plurality of disclosed patentably distinct species consisting of saline, dextrose, water, glycerol, ethanol, and combinations of saline, dextrose, water, glycerol, and ethanol. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate

status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg
May 10, 2003

RAM SHUKLA
PRIMARY EXAMINER